Biotech Daily

Friday August 27, 2021

Daily news on ASX-listed biotechnology companies

*** ASX FLAT, BIOTECH DOWN: CLINUVEL UP 18%; PATRYS DOWN 9%**

*** DR BOREHAM'S CRUCIBLE: CLARITY PHARMACEUTICALS**

*** MAYNE REVENUE DOWN 12% TO $401m, LOSS UP 125% TO $208m**

*** REDHILL H1 REVENUE UP 92% TO $58m, LOSS UP 57% TO $72m**

*** CLINUVEL REVENUE UP 43% TO $48m, PROFIT UP 68% TO $24.7m**

*** AVITA REVENUE UP 66% TO $43m, LOSS DOWN 37% TO $36.5m**

*** ATOMO REVENUE UP 25% TO $6.7m, LOSS DOWN 35% TO $6m**

*** ANTERIS H1 REVENUE DOWN 20% TO $3.2m, LOSS UP 74% TO $10m**

*** ALLEGRA REVENUE DOWN 10.2% TO $4.5m, LOSS DOWN 50% TO $579k**

*** MICRO-X REVENUE DOWN 11% TO $3.8m, LOSS UP 46% TO $14.7m**

*** TOTAL BRAIN REVENUE DOWN 4.7% TO $3.7m, LOSS UP 9% TO $8.3m**

*** CRONOS REVENUE UP 14-FOLD TO $1.7m, LOSS UP 3% TO $4m**

*** IMUGENE DOSING 3rd PD1-VAXX COHORT**

*** RHINOMED: ROYAL CHILDREN'S HOSPITAL TRIALS RHINOSWAB JUNIOR**

*** OSTEOPORE SPONSORS 2 PCL-TCP RECONSTRUCTION TRIALS**

*** IMMUTEP: CHINA PATENT FOR LAG525**

*** PAINCHEK DISPUTES $1.4m NSW TAX ASSESSMENT**

*** NEXT SCIENCE: IRRIMAX XPERIENCE SURGICAL WASH LEGAL ACTION**

*** EMYRIA: CALVERT FOR EMD-003 SYNTHETIC CANNABIDIOL STUDIES**

*** MGC CLAIMS $33m AMC MARIJUANA, CIMETRA DEAL**

*** FRANK CONDELLA REPLACES MAYNE CHAIR ROGER CORBETT**

MARKET REPORT

The Australian stock market slipped 0.04 percent on Friday August 27, 2021, with the ASX200 down 2.9 points to 7,488.3 points. Ten of the Biotech Daily Top 40 stocks were up, 23 fell, six traded unchanged and one was untraded.

Clinuvel was the best, up $5.25 or 17.95 percent to $34.49, with 787,224 shares traded. Antisense was up 8.8 percent; Avita improved 7.6 percent; Kazia climbed 4.55 percent; Immutep and Oncosil rose more than two percent; CSL, Imugene and Next Science were up one percent or more; with Genetic Signatures, Resmed and Telix up by less than one percent.

Patrys the falls, down 0.4 cents or 9.1 percent to four cents, with 15.1 million shares traded. Actinogen lost eight percent; Compumedics shed seven percent; Prescient, Resonance and Starpharma fell four percent or more; Alterity, Nanosonics and Pro Medicus were down more than three percent; Cyclopharm, Opthea, Optiscan, Orthocell, Paradigm and Polynovo shed two percent or more; Mesoblast, Neuren, Nova Eye, Universal Biosensors and Volpara were down one percent or more; with Cochlear, Cynata, Medical Developments and Proteomics down by less than one percent.

DR BOREHAM'S CRUCIBLE: CLARITY PHARMACEUTICALS

By TIM BOREHAM

ASX code: CU6

Share price: $1.475; **Shares on issue:** 256,132,546; **Market cap:** $377.8 million

Financials (December half 2020): revenue $1.38 million (up 14%), net loss $4.85 million (previous $3.29 million deficit), cash post raising $104m

Chief executive officer: Dr Colin Biggin

Board: Dr Alan Taylor (executive chair), Dr Chris Roberts, Dr Thomas Ramdahl, Dr Gillies O'Bryan-Tear, Rosanne Robinson, Rob Thomas

Identifiable major shareholders*: TM Ventures Pty Ltd 7.3%**, Dr Chris Roberts 7%, Dr Alan Taylor 5.5%, Charles Morgan 4.8%, Genesiscare Ventures 4%

***** China Grand will hold approximately 8.5 percent of the company if it exercises its 25,543,912 options

****** An entity associated with Clarity chief scientific officer Dr Matt Harris

In the spirit of the recently-concluded Olympics and ongoing Paralympics, congratulations to the backers of the radiopharmaceuticals group for a record-breaking performance after listing this week.

In raising $92 million, Clarity was the biggest biotech initial public offer (IPO) in ASX history - and being underwritten it was never in doubt.

Clarity pips the $50 million raised by imaging and diagnostics peer Telix Pharmaceuticals, when it listed in November 2017.

The record biotech IPO was that of bio-resorbable stent outfit Reva Medical, which raised $85 million in late 2010, but delisted in mid-2019.

No doubt many investors will view Clarity as the mini-me version of Telix, now valued at almost $2 billion.

While their tech differs, both companies are deploying isotopes in an innovative manner for detecting and treating tumors.

“Radiopharmaceuticals are hot, in more ways than one,” says executive chair Dr Alan Taylor.

Some clarity on Clarity

Clarity’s reason for being is simple enough: “to achieve superior imaging and highly precise and accurate therapy”.

Clarity’s intellectual property revolves around two radioisotopes: copper-64 and copper-67. The former is for improved PET (positron emission tomography) scanning and the latter is for, like, actual therapy.

Not to be confused with icy-poles or isobars, isotopes are derivatives of an element on the periodic table that share the same number of protons but have a different number of neutrons.

At the heart of the technology is a stable functional ‘cage’ called a chelator, which prevents the leakage of copper into the body. The cage is linked to a targeting molecule, which finds and binds specific receptor cancer cells.

Dr Taylor notes cancer treatments traditionally have revolved around surgery, radiotherapy and chemotherapy

“With better understanding of the biology of tumors we have been able to target tumors with ‘warheads’: either drug conjugation, radiotherapy or immunotherapy,” he says.

These disciplines can be interlinked.

In a two-fold process, copper-64 is used to image the patient. If enough of the agent accurately hits the tumor, the patient is then eligible for copper-67 therapy if the copper doesn’t leak to the liver (where it is metabolized).

“There’s a lot of product that gets to the tumor and stays there,” Dr Taylor says. “Then we zap the tumor and [the copper] is excreted through the kidneys.”

Background briefing

Clarity's tech derived from the University of Melbourne and the Australian National University (ANU), with a little help from the Australian Nuclear Science and Technology Organisation (ANSTO).

Dr Taylor trained at the Garvan Institute in Sydney but then was lured into investment banking, where he was involved in large life science IPOs as head of Inteq Ltd.

In 2013, he moved on to focus on commercializing "good Australian science".

Clarity was formed in 2010, based on the chelator development work of two luminaries: the late Dr Alan Sargeson at Australian National University and Prof Paul Donnelly at Melbourne Uni's Bio21 Institute of Molecular Science and Technology.

"When I joined Clarity it had no more than a couple of patents pending, with no employees and no money," Dr Taylor says.

Now with about 20 employees, Clarity is Sydney based with subsidiaries in Belgium and the US.

CEO Colin Biggin was the tenth employee of Norwegian radiotherapy pioneer Algeta ASA and was central to commercializing the company's commercial product for metastatic prostate cancer, Xofigo (radium-223 dichloride).

Clarity board member Dr Thomas Ramdahl was Algeta's first CEO and was there when Bayer AG acquired the company for $US2.9 billion in 2014. Fellow director Dr Gillies O'Bryan was Algeta's chief medical officer.

Rosanne Robinson was ANSTO's business development chief. Rounding out the Clarity board table are former Cochlear chief Dr Chris Roberts and former Citibank Australia chief Rob Thomas (who is also chairman of Starpharma and a Biotron director).

It's SAR good for many things

Clarity is based around its SAR (stereotactic ablative radiotherapy) platform, with its work revolving around six diagnostics and therapies covering breast cancer, prostate cancer and neuroblastoma in children.

The neuroblastoma program, Sartate, was subject to phase I trials in 2015 and is the most advanced.

A trial at Melbourne's Peter MacCallum Cancer Centre compared copper-64 against a gallium-based product, the standard of care for such tumors.

With a half-life of only one hour, gallium poses logistics and imaging issues.

Because copper-64 has a half-life of 12.7 hours, it can measure effects over time.

In the US, Clarity has been granted investigational new drug status for two indications and also has two rare paediatric disease designations for diagnosing and treating kids' neuroblastoma.

Under an investigational new drug (IND) protocol in the US, Clarity is running a phase I/II dose-escalation study for children's neuroblastomas at five sites.

SAR-Bombesin is relevant for numerous cancers, but a trial at St Vincent's Sydney zeroed in on breast cancer (targeting the commonly-expressed gastrin-releasing peptide receptor).

"We are getting very important data right from day one with our imaging," Dr Taylor says.

Separately, Clarity has begun its 'Propeller' trial of copper-64 (64-Cu) SAR-bis-PSMA for prostate cancer at Perth's Genesiscare and Sydney's Nepean Hospital.

The 30-patient, phase I, PET imaging trial of patients with confirmed prostate cancer is blinded review, dose-ranging, non-randomized study prior to radical prostatectomy.

Clarity describes the pre-clinical data as "compelling", with both higher tumor uptake and greater tumor retention compared to current rival products.

Clarity is also running a US prostate cancer trial called Secure and just ahead of listing this week the company announced it had enrolled its first patient.

Eyes on the supplies

Radioactive isotopes don't just grow on trees, so procuring adequate supply is the key to commercialization.

Copper-64 can be mass produced on cyclotrons (particle accelerators).

"I have two within walking distance from me in Redfern [part of the inner Sydney university precinct] which means the isotopes can be produced and distributed overnight to anywhere where there's a PET camera," Dr Taylor says.

Copper-67 isotopes are produced on linear accelerators, which are found in most hospitals (Rhodotrons are a new powerful version).

The competing and commonly used isotope lutetium-177 needs to be produced in a nuclear reactor, which unlike 7-Elevens are not exactly on every corner.

Clarity has entered an agreement with the Wisconsin-based Northstar Radioisotopes for supply of copper-67 isotopes.

Finances and performance

It's too early to opine on Clarity's finances or performance, but suffice to say the $92 million banked should go some way to road-testing the isotopes - with a few bob left over for icy-poles.

Given the company already had $17 million in the bank, its war chest exceeds $100 million, with circa $44 million from China Grand options potentially yet to come (see below).

Pre IPO, Clarity raised $40 million to $50 million from investors, with a further $10 million or so from government grants.

On listing, the shares ran out of the blocks to a day's high of $1.71, a 22 percent premium.

Ain't it (China) Grand

A quirk of Clarity's register is that its biggest would-be holder is just that - prospective.

China Grand Pharmaceuticals has an enduring interest in the Australian radio-pharmaceuticals sector, having prevailed in the three-way tussle for targeted radiation innovator Sirtex Medical. The eventual price tag was $1.9 billion.

China Grand last year struck a $450 million partnering deal with Telix.

China Grand holds just over 25.5 million options in Clarity, equivalent to circa 8.5 percent of the company if converted to ordinary shares.

But there are two conditions to China Grand exercising its options. One is that Clarity lists (tick) and the other is that the duo enter a distribution deal for greater China.

China Grand has six months exclusive negotiating rights. If the deal is done, China Grand exercises the options at $1.75 apiece - a 25 percent premium on the listing price. This would inject a further $44.6 million into the company.

Dr Taylor says: "Our products are ideal for the China, given the size of the market and the opportunity to mass produce isotopes."

The Gibb brothers would be proud

The Bee Gees might have started a joke that got the whole world crying.

In the case of Dr Chris Behrenbruch at Telix , he started an ASX trend that has kept biotech investors smiling to date.

There's more to come. Backed by biotech entrepreneur Paul Hopper, a private mob called Radiopharm Theranostics***** plans to raise $50 million and list on the ASX in November.

The company is based on combined technologies licenced from Imperial College London, New York's Sloan Kettering Memorial Hospital and the Technical University of Munich.

More broadly, investor interest has been piqued by two transactions involving Novartis over the last three years.

Firstly, the Swiss drug giant acquired Endocyte for $US2.1 billion and then snapped up Advanced Accelerator Applications (AAA) for $US3.9 billion.

AAA has a therapy for neuro-endocrine tumors, while Endocyte is in phase III stage of developing a prostate cancer treatment, PSMA-617. Both are lutetium based.

Dr Boreham's diagnosis:

Dr Taylor is pleased with Clarity's pneumatic share price, but he's not going to be gazing at the ASX screen all day.

"The day-to-day share price fluctuations are a little bit less relevant for us than our clinical plans over the next couple of years," he says.

"We're incredibly excited about the five clinical trials we are running right now and the drive into the US."

We concur that opportunities abound in a sector that's well developed in the US and Europe, but has had surprisingly little innovation.

For Clarity, it's a case of remaining focused on the aforementioned key oncology targets and the highly potential market for niche childhood cancers such as neuroendocrine tumors.

"Because we have a platform technology, we are not limited to the products we focus on," Dr Taylor says. "We could produce 20 or 40 products, but focus is the key for us."

He adds: "Clarity is very much an Australian story and we are keen to keep it in Australia for as long as we can."

Great to see that one doesn't have to drape the flag around oneself at Cronulla beach to be a true patriotic flag waver …

***** "Theranostics" is a gruesome made-up word for the combination of diagnosis and therapeutics. The term is usually banned in this publication, but as it's part of an official company moniker we need to make a grudging exception in this case.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He's convinced that while you don't need to be a rocket scientist to understand nuclear medicine it sure would help.

MAYNE PHARMA GROUP

Mayne says revenue for the year to June 30, 2021, fell 12.3 percent to $400,781,000 with net loss after tax up 124.6 percent to $208,400,000.
Mayne said revenue came from the sale of a range of generic pharmaceuticals.
Mayne chief executive officer Scott Richards said results were impacted by foreign exchange, the Covid-19 pandemic and “challenges in the US retail generic sector”.
The company said diluted loss per share was up 118.5 percent to 13.26 cents, with net tangible assets per share up 60.0 percent to 8.0 cents per share compared to 5.0 cents at June 30, 2020.
Mayne said it had cash and cash equivalents of $97,980,000 at June 30, 2021, compared to $137,785,000 at June 30, 2020.
Mayne fell 3.5 cents or 11.9 percent to 26 cents with 24.2 million shares traded.

REDHILL BIOPHARMA

Redhill says revenue for the six months to June 30, 2020 rose 91.7 percent to $US42,077,000 ($A58,145,860) with net loss after tax up 56.6 percent to $US51,984,000 ($A71,848,658).
In 2010, Israel's Redhill bought Myoconda (RHB-104), Heliconda (RHB-105) and Picoconda (RHB-106) from Sydney's Giaconda (BD: Aug 17, 2010).
Today, Redhill said that revenue came from sales of Movantik for opioid-induced constipation and Talicia, formerly Heliconda for Helicobacter pylori infections.
The company said that diluted loss per share was up 33.3 percent to 12.0 US cents, compared to 9.0 US cents in the previous corresponding period.
Redhill said it had cash and cash equivalents of $US51,816,000 at June 30, 2021 compared to $US22,272,000 at June 30, 2020.
On the Nasdaq, Redhill was up 11 82 US cents or 1.53 percent to $US7.29 ($A10.07) with 2.9 million shares traded.

CLINUVEL PHARMACEUTICALS

Clinuvel says revenue for the year to June 30, 2021 was up 42.9 percent to $48,451,000 with net profit after tax up 64.3 percent to $24,728,000.
Clinuvel said revenue came from sales of its Scenesse treatment for erythropoietic protoporphyria (EPP) in the US and Europe.
Clinuvel chief financial officer Darren Keamy said that “the progress in the US in the first full year of commercial operations is ahead of our planning, with over 40 specialty centers trained and accredited to administer Scenesse and over 60 national and state private insurers reimbursing EPP patients’ treatment”.
“The company’s cash reserves allow us to declare a dividend today to recognize the loyalty of long-term shareholders, while still being in a position to finance our planned organic expansion,” Mr Keamy said.
Clinuvel said it would pay an unfranked dividend of 2.5 cents a share to holders on the record date of September 3 to be paid on September 17, 2021, which was the same as last year.
The company said diluted earnings per share rose 62.4 percent to 48.4 cents, with net tangible assets up 41.5 percent to $1.91.
Clinuvel said it had cash and cash equivalents of $82,691,000 at June 30, 2021 compared to $66,747,000 at June 30, 2020.
Clinuvel climbed $5.25 or 17.95 percent to $34.49 with 787,224 shares traded.

AVITA THERAPEUTICS

Avita says revenue for the 12 months to June 30, 2020 was up 65.8 percent to $US31,304,000 ($A43,148,310) with net loss after tax down 37.1 percent to $US26,470,000 ($A36,493,090).
Avita said that revenue from its Recell spray-on-skin system for burns was up 49.5 percent to $US21,500,000, with revenue from the US Biomedical Advanced Research and Development Authority contract up 40.7 percent to $US7,700,000.
The company said diluted loss per share was down 43.5 percent to $US1.17 cents, net tangible asset backing per share rose 36.2 percent to $US4.57, and cash and equivalents of $US110,746,000 at June 30, 2021 compared to $US73,639,000 in 2019.
Avita was up 38 cents or 7.6 percent to $5.36 with 897,294 shares traded.

ATOMO DIAGNOSTICS

Atomo says revenue for the year to June 30, 2021 was up 25.1% to $6,715,659 with net loss after tax down 34.7 percent to $6,021,215.
Atomo said revenue was driven by demand for its Covid-19 antibody tests in Europe and North America, as well as sales of Covid-19 rapid antibody tests and severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2) antigen tests in Australia.
The company said diluted earnings per share was down 58.7 percent to 1.07 cents, net tangible asset backing per share fell 22.6 percent to 4.76 cents and it had cash and equivalents of $17,946,517 at June 30, 2021 compared to $27,103,838 at June 30, 2020.
Atomo fell half a cent or two percent to 24 cents with 4.6 million shares traded.

ANTERIS TECHNOLOGIES

Anteris says that revenue for the six months to June 30, 2019, was down 19.6 percent to $3,173,787 with net loss after tax up 73.5 percent to $10,358,138.
Anteris said the revenue came from sales of its Adapt-treated cardiac repair products.
The company said that diluted loss per share rose 56.0 percent to 157.6 cents at June 30, 2021, with net tangible asset backing per share down from 131.7 cents last year to negative 75.7 cents at June 30, 2021.
The company said it had cash and cash equivalents of $3,145,835 at June 30, 2021 compared to $4,354,355 at December 31, 2020.
Anteris fell 35 cents or 3.8 percent to $8.95.

ALLEGRA ORTHOPAEDICS

Allegra says revenue for the year to June 30, 2021, fell 10.2 percent to $4,501,218 with net loss after tax down 50.3 percent to $578,845.
Allegra said revenue came from sales of orthopaedic products and fell due to the decreased elective surgery rates in Victoria and New South Wales.
The company said that 60.7 percent of its consolidated external revenue came from two major hospital groups.
Allegra said that diluted loss per share was down 53.0 percent to 0.55 cents, with net tangible assets per share down 13.9 percent to 3.64 cents per share compared to 4.23 cents at June 30, 2020.
Allegra said it had cash and cash equivalents of $363,223 at June 30, 2021, compared to $755,592 at June 30, 2020.
Allegra was unchanged at 25 cents.

MICRO-X

Micro-X says that revenue for the 12 months to June 30, 2019, was down 11.3 percent to $3,771,000 with net loss after tax up 46.3 percent to $14,731,000.
Micro-X said the revenue came from its mobile hospital and defence x-ray products.
The company said diluted earnings per share fell 14.9 percent to 3.70 cents, net tangible asset backing per share was up 183.8 percent to 7.38 cents per share and it had cash and equivalents of $30,135,000 at June 30, 2021 compared to $18,318,000 at June 30, 2020.
Micro-X was up half a cent or 1.9 percent to 27 cents.

TOTAL BRAIN

Total Brain says revenue for the year to June 30, 2021 was down 4.7 percent to $3,694,268 with net loss after tax up 8.8 percent to $8,316,773.
Total Brain said decreased revenue from its mental health assessment systems was due to delays in the execution of US government contracts following the presidential election.
The company said the Covid-19 pandemic had led to “an unprecedented increase in stress, fear and anxiety … making mental health an urgent priority … [but it had] mobilized to take advantage of the opportunities that this pandemic has created”.
The company said diluted loss per share was down 4.8 percent to 7.68 cents, net tangible assets per share fell 91.7 percent to 0.87 cents, and it had cash and cash equivalents of $1,427,349 at June 30, 2021 compared to $11,104,729 at June 30, 2020.
Total Brain was up one cent or 4.3 percent to 24.5 cents.

CRONOS AUSTRALIA

Cronos says revenue for the year to June 30, 2021 was $1,692,840 compared to $123,850 in 2020, with net loss after tax up 2.8 percent to $4,049,209.
Cronos said revenue was driven by sales of its marijuana products and expanding its Cannadoc medical clinic business in Australia and New Zealand.”
The company said diluted loss per share was down 25.0 percent to 3.0 cents, net tangible asset backing per share fell 32.7 percent to 6.8 cents and it had cash and equivalents of $9,647,175 at June 30, 2021 compared to $14,685,943 at June 30, 2020.
Cronos was unchanged at 11 cents.

IMUGENE

Imugene says that three patients are being dosed in the third monotherapy cohort of its phase I PD1-Vaxx immunotherapy trial (BD: Apr 7, 2021).
Imugene said that it expected the optimal dose of 100µg to be ratified at the next cohort review committee meeting scheduled for the first week of October.
The company said that PD1-Vaxx was “showing early signs of an immune response in patients, with antibodies to the target biomarker PD-1 evident in validated assays”.
Imugene said that the first-in-human, phase I, dose-escalation study of PD1-Vaxx was recruiting patients with non-small cell lung cancer, and testing three different doses of PD1-Vaxx, with the primary goal to determine safety and an optimal dose as a monotherapy (BD: Dec 17, 2020; Jan 21, Feb 12, 2021).
Imugene was up half a cent or 1.5 percent to 34.5 cents with 33.2 million shares traded.

RHINOMED

Rhinomed says it produced “the world's first nasal swab designed specifically for children” and the Rhinoswab Junior will be trialled at Melbourne’s Royal Children’s Hospital.
Rhinomed said that the trial at the Murdoch Children’s Research Institute would investigate the diagnosis of respiratory viruses in children with Rhinoswab Junior, which was designed to collect a nasal sample from children without the discomfort and distress often associated with the combined throat and deep nasal swabs.
The company said that the Rhinoswab Junior was a smaller version of the Rhinoswab device “with child friendly features to engage children in the sampling process”.
Earlier this month, Rhinomed said that New South Wales Health Pathology ordered one million Rhinoswabs for severe acute respiratory syndrome coronavirus 2 (Sars-Cov-2) testing (BD: Aug 11, 2021).
Today, the company said its Rhinoswab design allowed for standardization of the site of biological sampling, as compared with standard swabs, which were operator dependent.
Rhinomed said that the diagnostic validation study would evaluate the Rhinoswab, self-collection anterior nasal swab as an alternative method to combined throat and deep nasal swab for respiratory sample collection in children aged four to 18 years.
The company said that study aimed to recruit 250 children at the Hospital’s respiratory infection clinic with the standard swab sample collected by a healthcare worker and children to self-collect the Rhinoswab sample under supervision.
Rhinomed was up six cents or 18.75 percent to 38 cents with 14.1 million shares traded.

OSTEOPORE

Osteopore says it will sponsor two trials of 10 patients each in Brisbane to evaluate and validate the clinical use of its cranial and long bone reconstruction scaffolds.
Osteopore said that Brisbane’s Dr Michael Wagels would lead a team of surgeons to study its three-dimensional-printed medical grade poly-caprolactone-tricalcium phosphate (PCL-TCP) scaffolds and the surgical technique used to implant them in patients.
The company said that the trial would run for up to five years and was instigated after encouraging results in several first-in-human cases, including reconstruction of two tibias, one midface, two mandibles and one skull.
Osteopore said that patients would be treated at Brisbane’s Princess Alexandra Hospital and supported by the Herston Biofabrication Institute, with expansion planned to the Royal Brisbane and Women’s Hospital.
The company said that one study would evaluate its PCL-TCP scaffold with cortico-periosteal tissue transfer for the reconstruction of acquired calvarial or upper cranial defects in adults.
Osteopore said that the second study will evaluate the PCL-TCP scaffold system with cortico-periosteal tissue transfer for the reconstruction of critical-sized lower limb bone defects.
Osteopore chief technology officer Dr Lim Jing said the trials were “an important milestone in the development of our second-generation regenerative implants”.
“This study aims to clinically validate our regenerative solution for cranioplasty, and cements our standing in the field of in-situ tissue engineering,” Dr Jing said.
Osteopore was up half a cent or 1.5 percent to 34 cents.

IMMUTEP

Immutep says that China's patent office has granted two patents related to its LAG525, a humanized form of its IMP701 antibody licenced to Novartis AG.
Immutep said that the patent, titled 'Antibody molecules to LAG-3 and uses thereof" followed the grant of the corresponding Australian, US, European, and Japanese patents and would provide intellectual property protection until March 13, 2035.
The company said the claims were directed to LAG525, compositions comprising LAG525, nucleic acid molecules that code for the LAG525 antibody, an expression vector or host cell that comprises the nucleic acid molecules, and to the use of LAG525 in the manufacture of a preparation for the treatment of cancer or infectious disease.
Immutep said that the patent was co-owned by Novartis AG and Immutep SAS.
Immutep was up 1.5 cents or three percent to 52 cents with 3.8 million shares traded.

PAINCHEK

Painchek says it disputes a New South Wales Office of State Revenue notice of assessment of about $1.4 million which includes about $200,000 in penalty tax.
Painchek said the Office assessed its 2016-'17 financial year payroll tax compliance and issued the notice, it disputed the assessment and had lodged an objection, having taken legal advice.
The company said that in 2020, it made a voluntary disclosure and paid about $86,000 in additional payroll tax to the Office of State Revenue in respect of the matters raised in the notice of assessment.
Painchek said it made "no admission whatsoever … [but would] act prudently and conservatively by making a provision of $1.4 million to cover this assessment in the 2020-'21 statutory accounts unless the matter is resolved in our favor".
The company said that while the assessed amount was not budgeted and was material, its cash reserves at June 30, 2021 were $11.4 million and the assessment would not materially impact its operating plans.
Painchek fell 0.2 cents or 3.8 percent to 5.1 cents with 1.9 million shares traded.

NEXT SCIENCE

Next Science says that the Irrimax Corporation has filed a legal complaint alleging "common law unfair competition and false advertising regarding Xperience".
Next Science said that it "strenuously denies the allegations and intends to vigorously defend the complaint if and when it is served".
The company said the complaint had been filed in the US District Court for the Northern District of Georgia.
The Irrimax Corp website said that Irrimax was a subsidiary of the Lawrenceville, Georgia-based innovative Technologies Inc.
Next Science said it was a new entrant in the surgery irrigation market with Xperience, which was a US Food and Drug Administration-cleared no rinse antimicrobial solution.
The company said that it had "independent, third-party data showing the performance of Xperience compared with other in-market surgery irrigation products".
Next Science said that Irrimax was a supplier of a chlorhexidine wash, comprising 99.95 percent water and 0.05 percent chlorhexidine, to the surgery irrigation market.
The company said that it "stands by the independently verified performance of Xperience, strenuously denies the allegations and intends to vigorously defend the complaint".
Next Science was up 2.5 cents or 1.8 percent to $1.44.

EMYRIA

Emyria says it has hired Calvert Laboratories to design and conduct preclinical drug development and optimization programs on its synthetic cannabinoid drug programs.
Emyria said the Scanton, Pennsylvania-based Calvert work targeted registration with the US Food and Drug Administration and Therapeutic Goods Administration.
The company said that Calvert would conduct a range of pre-clinical studies to generate data enabling human clinical trials for its EMD-003 synthetic cannabinoid.
Emyria said that Calvert was a subsidiary of the Laval, Quebec-based Altascience Co, which would conduct the bio-analyses.
Emyria was up 0.25 cents or 1.3 percent to 19.75 cents.

MGC PHARMACEUTICALS

MGC says it has supply and distribution deal with AMC Holdings, with minimum orders of $US24 million ($A33.1 million) for its marijuana and artemisinin products over three years.
MGC said the agreement was its “first dedicated supply agreement” for the supply of marijuana pharmaceutical products into the US.
The company said that AMC was based in the US and would buy its marijuana-derived Cannepil, and Cognicann and its artemisinin and curcumin Cimetra products.
MGC said that AMC would be responsible for the clinical trial process in the US, including the recruitment of patients, and would undertake US marketing activities, as well as managing the import and warehousing of the products.
The company said that the agreement included a minimum $US3 million of sales in the first year, subject to AMC receiving a National Clinical Trial Number for an MGC product by the end of September 2021, enabling US hospitals to participate in trials.
The company said US sites would join the Cimetra program and the two companies would seek approval to distribute and issue Cannepil through Florida’s early access scheme.
MGC was up 1.7 cents or 43.6 percent to 5.6 cents with 95.7 million shares traded.

MAYNE PHARMA

Mayne says that directors Frank Condella and Ian Scholes will be appointed chair, and deputy chair, respectively, effective from September 30, 2021.
Mayne said that current chair Roger Corbett and director Bruce Mathieson would retire following the September board meeting.
The company said that Mr Corbett had been a director since 2010 and chair since January 2011, and Mr Mathieson had been a director since 2007.
Mayne said that the Boston-based Mr Condella had more than 30 years’ experience, including as Juniper Pharmaceuticals, Skyepharma Plc and Faulding Pharmaceuticals chief executive officer.
The company said that Mr Condella held a Bachelor in Science and a Master of Business Administration from Boston’s Northeastern University.
Mayne said the Melbourne-based Mr Scholes had financial and corporate advisory experience and previously was Merrill Lynch Australia’s managing-director and vice chair of investment banking, was formerly National Australia Bank’s executive general-manager and was currently Chord Capital Pty Ltd chief executive officer.